Complete Summary

GUIDELINE TITLE

The role of calcium in peri- and postmenopausal women: consensus opinion of The North American Menopause Society.

BIBLIOGRAPHIC SOURCE(S)

The role of calcium in peri- and postmenopausal women: consensus opinion of the North American Menopause Society. Menopause 2001 Mar-Apr; 8(2):84-95. [104 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISCLAIMER

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Diseases and disorders associated with calcium requirements in peri- and postmenopausal women, including:

- Osteoporosis
- Colorectal cancer
- Hypertension
- Nephrolithiasis
- Obesity

GUIDFLINE CATEGORY

Assessment of Therapeutic Effectiveness Counseling Evaluation Prevention Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Nutrition
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Managed Care Organizations
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present an evidence-based consensus opinion regarding the role of calcium in peri- and postmenopausal women.

TARGET POPULATION

Peri- and postmenopausal women in North America

INTERVENTIONS AND PRACTICES CONSIDERED

Role of calcium in both skeletal and nonskeletal disorders in peri- and postmenopausal women

- 1. Osteoporosis. Effect of adequate calcium intake (with adequate vitamin D intake), either alone or with an antiresorptive agent, in reducing the rate of postmenopausal bone loss and in reducing the incidence of spine, hip, and other fractures.
- 2. Colorectal cancer. Chemoprotective effects of high calcium intakes on the proliferation of colorectal epithelial cells and the risk for colorectal adenoma development or recurrence.
- 3. Hypertension. Relationship between calcium intake and blood pressure in both hypertensive and normotensive women.

- 4. Nephrolithiasis. Effect of high calcium intake on the risk of developing renal calculi.
- 5. Obesity. Link between an increased risk of obesity and low calcium intake.

Calcium requirements for skeletal health

- 1. Calcium
- 2. Vitamin D
- 3. Magnesium

Assessment of calcium deficiency

- 1. Serum calcium
- 2. Urine calcium
- 3. Bone mineral density
- 4. Dietary calcium intake

Sources of calcium

- 1. Foods
- 2. Calcium-fortified foods
- 3. Supplements

MAJOR OUTCOMES CONSIDERED

Morbidity and mortality for calcium-associated conditions in periand postmenopausal women

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer searched MEDLINE (U.S. National Library of Medicine) for clinical trials evaluating the role of calcium supplementation in diseases and disorders related to peri- and postmenopausal women. References listed in primary sources as well as journal supplements, abstracts, and meeting presentations were also searched.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVI DENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The North American menopause Society (NAMS) appointed a panel of clinicians and researchers acknowledged to be experts in the field of calcium. Their advice was used to assist the NAMS Board of Trustees in developing this consensus opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This consensus opinion was reviewed by the Board of Trustees of The North American Menopause Society.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC)

Although the most definitive role for calcium in peri- and postmenopausal women is in bone health, it is clear that adequate calcium intake has implications that encompass a woman's overall health. Based on the available evidence, a strong statement can be made regarding the importance of ensuring adequate calcium intake in all women, particularly those in peri- or postmenopause.

 The Role of Calcium in Skeletal and Nonskeletal Diseases and Disorders Associated with Calcium Intakes in Peri- and Postmenopausal Women

A. Osteoporosis

Calcium, alone or with vitamin D, is not as effective in reducing menopause-related bone loss as are estrogen replacement therapy/hormone replacement therapy, selective estrogen-receptor modulators, or bisphosphonates. Calcium plus vitamin D can reduce the risk of fracture, particularly in the elderly, but it is no substitute for estrogen replacement therapy/hormone replacement therapy, selective estrogen-receptor modulators, or bisphosphonates in early postmenopausal women. However, calcium and vitamin D are both essential components of osteoporosis therapy with all antiresorptive agents.

B. Colorectal Cancer

Based on the generally consistent animal and human data, a case can be made that high calcium intake provides some chemoprotective properties against colorectal cancer. The data, however, are not sufficient to support a general recommendation that women take calcium solely to prevent colorectal cancer. However, since women should consume at least a minimum amount of calcium required for skeletal health, they may receive an added colorectal cancer benefit.

C. Hypertension

Trials have demonstrated that calcium intake is associated with a beneficial effect on hypertension. However, the data are not sufficient to support a general recommendation that women take calcium solely to prevent or treat hypertension. Women may experience an added hypertension benefit from consuming the minimum amount of calcium required for skeletal health.

D. Nephrolithiasis

Calcium intakes of up to 1,500 mg/day do not appear to increase the risk of developing renal calculi and probably reduce the risk appreciably. For peri- and postmenopausal women at high risk for developing renal calculi, foods may be the best sources of calcium. If calcium supplementation is needed, each dose should be taken with a large glass of water.

E. Obesity

Although limited data suggest a statistically strong, inverse correlation between the risk of obesity and dietary calcium intake, available studies indicate that calcium intake explains only a small portion of the variability in body weight in postmenopausal women. Nevertheless, as for the other nonskeletal disorders addressed in this consensus opinion, ensuring an adequate calcium intake for skeletal purposes may confer small weight-control benefits as well.

2. Optimal Intakes

Estimates of adequate intakes of calcium, vitamin D, and magnesium for periand postmenopausal women are based on evidence relating to osteoporosis prevention. At least 1,200 mg/day of calcium is required for most women; levels greater than 2,500 mg/day are not helpful. A daily intake of 400-600 IU of vitamin D is recommended, either through sun exposure or through dietary intake or a supplement. The current evidence does not support magnesium supplementation for most peri- and postmenopausal women who ingest a balanced diet.

- Assessment of Calcium Deficiency
 Since no accurate test to determine calcium deficiency exists, clinicians
 should focus instead on ensuring that a woman consumes enough calcium to
 meet the recommended levels through diet and, when necessary,
 supplementation.
- 4. Calcium Sources

Foods should be the primary source of calcium intake. Dairy products are among the best sources of calcium based on their high elemental calcium content, high absorption rate, and low cost relative to total nutritional value. Supplements and fortified foods are an alternative source for women not able to consume enough dietary calcium. Although achieving adequate calcium intake is the primary goal, a level of caution may be needed to avoid consuming more than 2,500 mg/day, owing to the abundance of supplemental calcium sources.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The consensus opinion was based on review of clinical trials evaluating the role of calcium supplementation in diseases and disorders related to peri- and postmenopausal women. When the evidence was contradictory or inadequate to form a conclusion, expert opinion-based decisions were made.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The best attested role of calcium in peri- and postmenopausal women is in bone health. Adequate calcium intake (in the presence of adequate vitamin D intake) has been shown to prevent bone loss and reduce fracture risk in peri- and postmenopausal women. Although calcium is not as effective as antiresorptive agents (such as, estrogen, selective estrogen-receptor modulators, or bisphosphonates), it is an essential component of antiresorptive agent therapy for osteoporosis.

Subgroups Most Likely to Benefit:

Calcium has been associated with beneficial effects in several nonskeletal disorders, primarily hypertension, colorectal cancer, obesity, and nephrolithiasis.

POTENTIAL HARMS

Calcium:

The use of higher calcium intakes produces no currently recognized health benefits to women, and side effects can occur. Intakes greater than 2,500 milligrams per day can increase the risk for hypercalcemia, which, in extreme cases, can lead to kidney failure.

Vitamin D:

The safe upper limit of vitamin D is 2,000 IU/day. Higher doses may introduce risks such as hypercalciuria and hypercalcemia, and should be avoided.

CONTRAINDICATIONS

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Calcium supplements should be considered contraindicated in women with a renal calculus until the specific cause has been determined and the woman reassessed.

QUALIFYING STATEMENTS

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- When a woman reaches menopause, calcium needs rise because of a
 decrease in the efficiency of utilization of dietary calcium, which is associated
 with the fall in ovarian estrogen production. The amount of calcium needed is
 also affected by the decrease in intestinal absorption that occurs with age.
 Some dietary factors can limit calcium absorption, including consumption of
 oxalic acid, large of amounts of grains that contain phytates (for example,
 wheat bran) and, possibly, tannins (found in tea).
- Because of the well-established need for adequate calcium intake, all
 participants in the key trials with either a selective estrogen-receptor
 modulator or a bisphosphonate received calcium supplements. Although it is
 likely that calcium potentiates the positive bone mineral density effects of
 these agents, as it does for estrogen replacement therapy/hormone
 replacement therapy, this conclusion can only be surmised.
- The effects and mechanisms of the beneficial effects of calcium in nonskeletal disorders have not been fully explored.
- Since no accurate test to determine calcium deficiency exists, clinicians should focus on ensuring that a woman consumes enough calcium to meet the recommended levels.
- Because osteoporosis is a complex disorder, maintaining an adequate calcium intake is just one aspect of a comprehensive skeletal health program for perior postmenopausal women.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Mar

GUIDELINE DEVELOPER(S)

The North American Menopause Society - Private Nonprofit Organization

SOURCE(S) OF FUNDING

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GUI DELI NE COMMITTEE

Expert Consensus Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Robert P. Heaney, MD (Chair); Bess Dawson-Hughes, MD; J.C. Gallagher, MD; Robert Marcus, MD; Jeri W. Nieves, PhD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from <u>The North</u> American Menopause Society (NAMS) Web site.

Print copies: Available from NAMS, P.O. Box 94527, Cleveland, OH 44101, USA Order forms are available at The North American Menopause Society [NAMS] Web site, www.menopause.org

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Boggs PP, Utian WH. The North American Menopause Society develops consensus opinions. Menopause 1998 Summer; 5(2):67-8.

Electronic copies: Available from <u>The North American Menopause Society (NAMS)</u> Web site.

Print copies: Available from NAMS, P.O. Box 94527, Cleveland, OH 44101, USA (Order forms are available at <u>The North American Menopause Society [NAMS]</u> Web site).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 7, 2001. It was verified by the guideline developer as of June 7, 2001.

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